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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,254	02/12/2004	Michael R. S. Hill	P-9485.05	5396

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EXAMINER	
SMITH, TERRI L	
ART UNIT	**PAPER NUMBER**
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,254	HILL ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-28-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (Claims 1–11) in the reply filed on 21 February 2007 is acknowledged. The traversal is on the ground(s) that the process claimed in Group I and the apparatus claimed in Group II are so inextricably related that the inventions should be examined in the same application. A search of the prior art generally relating to a method including esophageal stimulation of a vagal nerve and epicardial stimulation of a heart would also require a search of the prior art generally relating to apparatuses operable to perform esophageal nerve stimulation and cardiac stimulation. As a result, Applicants respectfully submit that examination of both Groups I and II would not create a serious burden on the Examiner. This is not found persuasive because as Examiner stated in the Office Action mailed on 11 January 2007, the apparatus as claimed can be used to practice another and materially different process such as not requiring reducing esophageal and endotracheal stimulation of the vagal nerve, but rather maintaining a steady stimulation on the SA node.

The restriction is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

2. The information disclosure statement filed on 28 June 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because document 5,546,655 lists an incorrect issue date and inventor name; and document 6,184,239 is indicated as a patent document withdrawn and there is no document shown for this document number. It has been placed in the application file, but the information referred to herein above has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information

contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

3. The disclosure is objected to because of the following informalities: On pages 14 –21 (excluding page 19) reference characters 10A, 10B, 10C, 10D and 10E are used to refer to several different elements in the drawings. None of these reference characters are shown in any of the drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

5. Claims 1–11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In claim 1, the phrase "esophageal stimulation" and "epicardial stimulation" should be in the active voice such as, "providing esophageal stimulation to a vagal nerve" and "providing epicardial stimulation."

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2, 4–7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke et al., U.S. Patent 5,571,150 and in view of Trailer, U.S. Patent 5,387,232.

9. Regarding claims 1, 4–5, 7 and 11, Wernicke et al. disclose esophageal stimulation of a vagal nerve to adjust the beating of a heart to a first condition (e.g., FIG. 2, element 23; ABSTRACT, lines 18–20); performing a medical procedure on an organ (e.g., FIG. 6; column 2, lines 7–13, where it is the Examiner's position that the organ is the vagus nerve and the medical procedure is the stimulation of it with the programmed signal after the previous conditions in the flow chart are met in FIG. 6); reducing esophageal stimulation of the vagal nerve (e.g., column 5, lines 39–41; column 8, lines 10–16; column 6, TABLE II; NOTE: It is the Examiner's position that each of these cited references show the slowed stimuli of the vagal nerve for synchronization which meets the claimed limitation of reducing esophageal stimulation.); esophageal stimulation of a nerve a subsequent time in order to re-adjust the beating of the heart to the first condition (e.g., column 5, lines 45–66); and continuing a medical procedure (all claim 1 up to this point) and a medical procedure is selected from a group consisting of invasive procedures (claim 11)

(e.g., FIG. 6). Wernicke et al. do not disclose epicardial stimulation of the heart to adjust the beating of a heart to a second condition and reducing epicardial stimulation of the heart (claim 1) and delivering at least one drug during a medical procedure (claim 7). However, Trailer discloses epicardial stimulation of the heart to adjust the beating of a heart to a second condition (e.g., FIG. 3, elements 14 and 16; column 4, lines 50–55) and reducing epicardial stimulation of the heart (e.g., column 5, lines 16–22) and delivering at least one drug during a medical procedure (e.g., column 2, lines 15–17) to quickly and easily maintain the heart in a condition conducive to allowing a physician to perform a medical procedure accurately and expeditiously for optimum patient safety and to provide maximum patient comfort during the medical procedure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Wernicke et al. to include epicardial stimulation of the heart to adjust the beating of a heart to a second condition and reducing epicardial stimulation of the heart, as taught by Trailer to ensure accurate and reliable device function and maximum patient safety during a medical procedure.

10. With respect to claims 2 and 6, Wernicke et al. disclose esophageal stimulation is stopped to achieve a second condition and a second condition is a beating condition (e.g., FIG. 5 where it is the Examiner's position that SIGNAL OFF TIME represents the claimed limitation set forth in claim 2 and SIGNAL ON TIME to the right of SIGNAL OFF TIME represents the claimed limitation set forth in claim 6.)

11. Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke et al. and Trailer as applied to claims 1 and 7 above, and further in view of Atlee, III, U.S. Patent 5,370,679.

12. Wernicke et al. and Trailer disclose the essential features of the claimed invention as disclosed above except for epicardial stimulation is stopped to re-adjust the beating of the heart to the first condition (claim 3) and a drug is selected from a group consisting of a local anesthetic (claim 8). However, Atlee, III discloses epicardial stimulation is stopped to re-adjust the beating of the heart to the first condition (e.g., column 7, lines 64–68 where it is the Examiner's position that with the pace signal being applied through the electrode on carrier 182 alone represents the re-adjust limitation of the claimed invention and a stopped epicardial stimulation is the stopped pacing of carrier 180 in this scenario while the re-adjust limitation is being met) and a drug is selected from a group consisting of a local anesthetic (e.g., column 6, lines 31–34 where it is the Examiner's position that Atlee, III's tropical anesthetics is by definition the same as the local anesthetic as set forth in Applicant's claimed limitation) to ensure optimum heart function for maximum patient safety during the medical procedure and to ensure maximum patient comfort. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Wernicke et al. and Trailer to include epicardial stimulation is stopped to re-adjust the beating of the heart to the first condition and a drug is selected from a group consisting of a local anesthetic, as taught by Atlee, III to ensure optimum heart function for maximum patient safety during the medical procedure and to ensure maximum patient comfort.

13. Claims 9–10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke et al., Trailer and Atlee, III.

14. Wernicke et al., Trailer, and Atlee, III disclose the essential features of the claimed invention as described above, except for a drug is naturally occurring (claim 9) and chemically synthesized (claim 10). Atlee, III discloses the use of a topical anesthetic, but does not expressly disclose that the drug is naturally occurring and chemically synthesized. However, one of ordinary skill in the art at the time the invention was made would have known to include a drug that is naturally occurring and chemically synthesized because it is well-known to use naturally occurring and chemically synthesized drugs during medical procedures to obtain and ensure maximum patient comfort and safety. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Wernicke et al., Trailer and Atlee, III to include a drug is naturally occurring and chemically synthesized to obtain and ensure maximum patient comfort and safety.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on 7:30 a.m. - 4:30 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
March 8, 2007

8 March 2007

[illegible] EVANISKO
PRIMARY EXAMINER

3/12/7